LCCS Single-Use RF Cannula Instructions For Use

I. Indication For Use

LCCS Radio-frequency Cannula (RF Cannula) is indicated for use in RF heat lesion procedures for the relief of pain.

II. General Description

LCCS RF Cannula is provided in straight, curved or curved blunt format with a stylet inserted in the cannula. Cannula is insulated except for the active tip. The active tip determines the size of the radiofrequency lesion. The stylet's hub color indicates the gauge of the cannula, as shown in the table below:

Gauge	Color
22G	Black
21G	Green
20G	Yellow
18G	Pink
16G	White

Note:

- For straight cannula, a black indicator mark on the cannula hub indicates the bevel opening.
- For curved and curved blunt cannula, a blue indicator mark on the cannula hub indicates the direction of the cannula's curve to enhance cannula location.

III. Directions for Use

Consult the "General Description" section for information regarding the location of the cannula's bevel opening.

- With Stylet in LCCS's RF Cannula, insert cannula into patient at the desired location using diagnostic imaging guidance. The Doctor should determine the appropriate depth of insertion.
- Remove the stylet.
- Insert the pre-sized RF denervation probe in the RF Cannula per the instructions for use provided with that device. Further locate the lesion point by using RF Generator and start lesion procedure.
- Upon completion of the procedure, remove the electrode and RF Cannula.
- Dispose of the RF Cannula properly.

IV. Contraindications

There are no known contraindications to the use of electrosurgery. Use in the presence of internal or external pacemakers and monitoring equipment may require special considerations (See "Warnings").

V. Precautions:

- Prior to use, inspect the product package for signs of damage or tampering. Do not use if damaged.
- Prior to use, inspect the cannula to ensure there is no peeling or cracking of insulation. If there is damage to the cannula, contact LCCS for exchange and analysis.
- The primary packaging should be opened under sterile environments and the product should be used on time. Pollution or damage of the product should be avoided before and during use.
- If it is found that a needle tube is bent, please do not continuously use it after straightening.
- Stylet should be fully seated in the cannula prior to insertion into the patient.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

VI. Warning:

- For single use only. Discard any open, unused product. Do not use after the expiration date.
- Potential hazard of nerve injury: only physicians well trained in RF pain management procedures should perform a radiofrequency procedure.
- Prior to each procedure, visually check the probe and cannula insulation for damage. Insulation damage can produce unwanted tissue heating and possible burns.
- Do not use cannula if the package is damaged.
- Ensure that a distance of at least 1.5cm remains between the cannula's hub and the patient's skin surface.
- Do not reuse, re-sterilize or modify RF Cannula. Any reusage, re-sterilization or modifications may compromise patient safety and efficacy of the device.
- Do not bend the cannula. Bending may damage cannula insulation and result in patient burns.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read all instructions carefully prior to use. Failure to properly follow instructions may lead to improper functioning of the device and may result in patient injury.
- Hazardous electrical output: this equipment is for use only by qualified medical personnel trained in the use of electrosurgery.
- Use the lowest generator settings necessary to perform the intended procedure.
- Percutaneous insertion of the RF denervation probes should be performed only in conjunction with the use of diagnostic imaging to confirm proper cannula placement.
- After use, the cannula should be collected and destructed.

VII. Side Effects

- The use of RF denervation probes requires cannula insertion into tissue that entails some risk of hemorrhage.
- Burns to the surgeon's hands are possible if the probe comes into contact with a metal instrument or surface.
- More side effects for the clinical application are unknown.

VIII. Technical Specifications

• Product name:	Single-Use RF Cannula
• Method of packing:	Vacuum Packaging
• Intended use time:	Single-use
• Sterilization methods:	Ethylene oxide sterilized
• Tip configuration:	Sharp, straight tip Sharp, curved tip Blunt, curved tip
• Material of needle tip:	Stainless steel (SUS304)
• Stiffness and toughness:	Comply with EN ISO 7864:1996, ISO 9626:1995.
• Dielectric:	Comply with IEC60601-2-2: 2009

IX. Handling and Storage

The cannula is provided in a sterile package. Cannula should not be bent or folded, as this may cause insulation damage. Cannula should be stored in a cool dry place, avoid exposure to extreme temperature.

X. Cleaning and Sterilization

- LCCS RF Cannula is disposable and intended FOR SINGLE USE ONLY.
- Do not attempt to clean or resterilize any LCCS RF Cannula.
- Discard used RF Cannula as biohazardous waste.

XI. Normalized Symbols

	Attention, see instructions for use!
	Sterilized using Ethylene Oxide
	Do not reuse
	Do Not Resterilize
	Do not use if package is damaged
	Catalogue Number / Part Number
	Batch code
	Use by
	For or By Order of a Physician
	Manufacturer information
	Consult instructions for use

XII. For Further Information

If further information on this product is needed, please contact LCCS customer service or authorized representative.

LCCS Products Limited
Address (HK): Office 3A- 7, 12 / F, Kaiser Center, No.18 Center Street, Sai Ying Pun, Hong Kong
Address (US): 16661 N. 84th Avenue, Suite 110, Peoria, AZ 85382 USA
Tel: +1 (844)743-6449
Email: info@lccsmedical.com Web: www.lccsmedical.com

EC REP Wellkang Ltd (www.CE-marking.eu)
29 Harley St., London W1G 9QR, UK